

## HL7 SPL Working Group Process Communication Forum Telecon

Wednesday, March 25, 2009

Check out the SPL Working Group WIKI @:

<http://spl-work-group.wikispaces.com>

### Meeting Minutes:

- 1) Packaging Requirements for SPL r4 – Principal Display Panel
  - a. Question was raised about inclusion of the jpeg of the “representative” packaging in the SPL.
    - i. The issue that requires further clarification is which packaging component should be included in the SPL. For instance, a packaging component may have multiple iterations of the same component to handle multiple manufacturing sites for the same product with the same NDC code (i.e., the only difference between the components being, “Manufactured by:”), under these circumstances, which packaging should be included? The other item discussed was if it would create confusion from the Drug Listing section since the drug listing section would list all registered establishments involved in the manufacturing process.
    - ii. **Action:** Discuss with Lonnie to determine if there are best practices for handling this scenario.
- 2) Initial SPL wiki survey results
  - a. Survey was distributed with the meeting agenda
    - i. Question was asked about NDC Labeler Code answer of 250, is this correct?
      1. Confirmed, this is what was answered in the survey, however, uncertain if a company actually has 250 NDC Labeler Codes (seems like an excessively high number)
- 3) Conversion from r3 to r4
  - a. Discussion:
    - i. Are people having any issues with converting? SetID issues?
      1. No one indicated they are having problems
- 4) Validation Issues with SPL files
  - a. Discussion:
    - i. Team requested to come up with different scenarios where it could cause validation issues. Scenarios discussed:
      1. Foreign manufacture of API should a full SPL be created? The product would have an NDC and shipper label, therefore wouldn't this trigger the need for a full SPL r4 submission, however, this may not be possible because the API may be used for multiple products.
      2. Export Labeling
        - a. Is the full content of the labeling required for Export Labeling?

- b. The labeling associated with the Export label may be in the local country format (i.e., not in English nor in the USPI format).
    - c. What would happen (validation-wise) if the full content of labeling is not submitted?
  - 3. Discontinuation of product strength
    - a. Delisting of product would occur
  - 4. Multiple NDAs for same product NDC
    - a. Which NDA does the sponsor put into the DL part of the SPL r4?
    - b. Should sponsors simply use the first NDA since the marketing start date is provided in the SPL?
- b. Recommendations/Resolution:
  - i. Team was requested to provide additional scenarios to Michael Fahmy ([michael.fahmy@bms.com](mailto:michael.fahmy@bms.com)), ERDL sub-team lead.

## **Sub team updates**

### **OTC update**

- Complete vendor presentations on Wiki
- No active agenda for 3/30 meeting (canceled meeting)
- Next meeting will be April 6<sup>th</sup>
  - Items to be discussed
    - Question's about private label distributors and manufactures will be discussed, to help with discussion Devon Morgan will attend

### **Generics**

- Minutes are posted on Wiki
  - D&B presentation – on-line request service
  - Q&A on minutes
- FDA has scheduled additional webinars for June, contact FDA if interested in attending
- Sponsor can continue to use the excel spreadsheet for non-electronic submissions after June 1 delist NDC codes
  - Companies can also use a spreadsheet to delist NDC codes for products that are listed twice in the FDA database. In the past, a company was required to drug list the manufacturer and the distributor of a product each with its own NDC number. So many products had duplicate numbers if both were at separate companies or locations. (same company, different countries). As a result, NDC for products that are ONLY manufactured at a specific site assigned with a labeler code will need to be delisted.

### **Medical Devices**

- April 17<sup>th</sup> 10am EST next meeting
  - SPL for Medical Devices in early stage
  - Update will be provided
- Contact Myron Finseth ([myron.finseth@medtronic.com](mailto:myron.finseth@medtronic.com)) if you are interested in attending the meeting

### **ER/DL**

- March 18<sup>th</sup> was the last meeting, minutes are posted on wiki
  - Re-occurring discussion – Export Only products
    - FDA will evaluate – however, continue to stress that no changes to regulations, therefore, companies should continue to what had been do in the past
  - Process Questions Log is being developed with specific scenarios (including validation issues) and will be posted to Wiki
- Next meeting is April 1<sup>st</sup> @ 10am EST
  - Contact Michael Fahmy ([michael.fahmy@bms.com](mailto:michael.fahmy@bms.com)) if you want to attend

### **Biologics**

- No update (Next meeting April 30<sup>th</sup>, 11-12 EST)

### **Vet Med**

- No update